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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,400	09/11/2003	Kenji Harano	14862Z	5852
23389	7590	02/23/2006	EXAMINER	
SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			PEFFLEY, MICHAEL F	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/660,400	<b>Applicant(s)</b> HARANO ET AL.	
	<b>Examiner</b> Michael Peffley	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 23-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/28/05</u> . | 6) <input type="checkbox"/> Other: _____  |

Applicant's amendments and comments, received December 23, 2005 have been fully considered by the examiner. In particular, applicant's amendments have obviated the claim objections and the terminal disclaimer filed with the response is acceptable and has overcome the double patenting rejection. The following is a complete response to the December 23, 2005 communication.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11-18 and 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV et al (5,817,093) in view of the teaching of Malis et al (5,318,563).

Williamson, IV et al disclose an electrosurgical system which includes a high frequency current generator (70) for delivering energy to tissue. There is also an output changing means (75/61 – see col. 12, lines 53+) and a control means (79) for controlling the output changing means. There is also a coagulation state judgment means (120) which monitors biomedical information (i.e. current, voltage, impedance) to determine the coagulated state of tissue. Feedback from the judgment means is used by the controller to control the delivery of energy to tissue. With specific regard to claim 23, the Williamson, IV et al system is capable of providing a variety of levels of energy level

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dependent upon the judged state of tissue coagulation, and Williamson, IV et al further disclose a second or "query" signal which is used to monitor tissue in between bursts of the treatment signal. Williamson, IV et al fail to specifically disclose that each successive power delivery interval is of equal to or shorter duration than an immediate prior interval.

Malis et al teach that it is generally known to delivery RF energy in a series of pulses in order to coagulate tissue. In particular, the pulses of energy (i.e. intermittent delivery of energy) are of uniform width (see Abstract). As such, Malis et al teach that it is known to provide intermittent delivery of RF energy over a plurality of time intervals wherein each successive power delivery time period is equal to (e.g. uniform width bursts) an immediate prior interval. The Malis et al electrosurgical system is substantially analogous to the Williamson, IV et al system in that it monitors tissue parameters, including impedance, to control the output of the generator for tissue coagulation procedures.

To have provided the Williamson, IV et al system with a generator that provides uniform pulse widths of RF energy for the treatment of tissue would have been an obvious consideration for one of ordinary skill in the art, particularly since Malis et al teach that it is known to use such a pulsed RF system in a feedback controlled coagulation system.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV et al ('093) and Malis et al ('563) and further in view of the teaching of Sherman ('994).

The combination of the Malis et al teaching with Williamson, IV et al has been established. Williamson, IV et al fail to specifically disclose a coagulated state judging means which acquires information during a plurality of pause periods during which output power delivery is discontinued.

Sherman discloses a very similar system, and specifically teaches that the RF output operates on a duty cycle (i.e. cycled on and off periods), and that the impedance of tissue may be monitored during pause or "off" periods. See column 8, lines 19+.

To have provided the Williamson, IV et al system, as modified by the teaching of Malis et al ('563), with a judging means which monitors tissue characteristics during off periods of an electrosurgical generator is deemed to be an obvious modification for one of ordinary skill in the art, particularly since Sherman teaches that duty cycle generators and off-period monitoring are well known in the electrosurgical arena.

### ***Response to Arguments***

Applicant's arguments filed December 23, 2005 have been considered but are not deemed persuasive.

Applicant continues to assert that Williamson discloses continuous power. The examiner maintains that Williamson merely fails to disclose the specifics of the power delivery, but that it is most likely similar to various other generators in the art that deliver RF energy to tissue in the form of pulses of energy (i.e. not continuously). Regardless, the examiner has provided a clear teaching in Malis et al that it is known to provide RF energy in the form of pulses whereby subsequent pulses are of equal time duration. Malis et al state in the Abstract that pulse bursts are provided having uniform widths (i.e.

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equal time duration). Applicant further contends that the Malis et al generator, which provides an aperiodic sequence, does not provide duty cycle control (applicant's arguments, page 12). However, Malis et al make reference to duty cycle control at numerous locations in the patent. See, for example, column 16, lines 20-25. Again, Malis et al teach that the pulse bursts have uniform width (time duration) ensuring that successive power delivery intervals (i.e. pulse bursts) have equal time duration to an immediate prior interval. It is noted that the pulse width modulator (PWM) of Malis affords control of the pulse durations which, as stated previously, is set to uniform lengths (i.e. durations). The examiner maintains that use of a well-known RF generator such as taught by Malis et al with the Williamson device would be an obvious consideration for one of ordinary skill in the art yielding the device set forth in the rejected claims.

Regarding intermittent energy delivery in RF systems, applicant is again alerted to the numerous references made of record in the prior office action. In particular, Buyse et al (6,398,779) discloses a pulsed system whereby parameters are measured during "off" periods of a pulse to control the output parameters for the next pulse. Parameters such as voltage, pulse duration, etc. are controlled. Figure 8 shows typical pulse forms that show successive pulses as having equal pulse durations. Again, Buyse et al, as with the other references cited in the previous Office action, are cited merely to illustrate the well known use of intermittent (i.e. pulsed) energy delivery as well as the control of pulse characteristics such as pulse duration.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

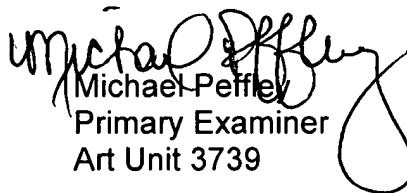
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael Peffley  
Primary Examiner  
Art Unit 3739

mp  
February 17, 2006